

**Appl. No.** : **09/787,356**  
**Filed** : **June 25, 2001**

## **REMARKS**

Claims 1, 20 and 22 have been amended and Claim 23 has been cancelled without prejudice. Claims 1, 2, 5-9, and 20-22 remain pending in the present application. Support for the amendments and new claims is found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter.

Applicants would like to initially thank Examiner Landsman for the courteous interview extended to Applicants' representatives, Daniel Altman and Connie Tong, on May 12, 2005. Applicants have amended the claims along the lines discussed during the interview. On the basis of the interview, and in response to the Office Action mailed December 28, 2004, Applicants respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

### Amendments to Specification

The Examiner objected to the specification for the following:

The Brief Description of Figure 5 was objected to since the word "shows" should not be plural.

The Brief Description of Figure 8 was objected to since it should begin by reciting "Figures 8A-8D."

The Brief Description of Figure 15 was objected to since it should begin by reciting "Figures 15A and 15D."

The Brief Description of Figure 19 was objected to since it should begin by reciting "Figures 19A-19D."

The specification has been amended to correct these informalities. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objections to the specification.

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Claim Objections

The Examiner rejected Claim 1 for syntax error in which “is” should be “are.” In view of the amendments to Claim 1, the present objection is now moot.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claim 1 under 35 U.S.C. § 112, second paragraph, because it recites an identifiable endpoint that does not relate back to the preamble. As suggested by the Examiner, the preamble of Claim 1 has been amended to recite “[a] method for mediating relaxation of an airway of an animal” so that the endpoint relates back to the preamble.

The Examiner rejected Claim 20 under 35 U.S.C. § 112, second paragraph. As suggested by the Examiner, Claim 20 has been amended to recite “is identified as capable of being useful.”

The Examiner rejected Claim 22 under 35 U.S.C. § 112, second paragraph. As suggested by the Examiner, Claim 22 has been amended to add the information of the table into the claim.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1, 2, and 5-9 under 35 U.S.C. § 112, first paragraph, for enablement and written description for the limitation “in which one or more amino acids is replaced with non-natural amino acid.” The Examiner believes that the breadth of the claim is excessive since every amino acid in SEQ ID NO:2 can be replaced with a different non-naturally occurring amino acid. As discussed at the interview with the Examiner, the amendment of Claim 1 to recite “an amino acid,” instead of “one or more amino acids” addresses enablement, written description, and new matter rejections under 35 U.S.C. § 112, first paragraph. Support for the amendment can be found in the specification at paragraphs [0094] and [0101]. The data provided in the Declaration submitted October 1, 2004 show the effectiveness of a large number of compounds encompassed within the scope of the claim. In particular, peptides numbered 3-

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20, 22-30, 46, 54, and 58 are all examples of peptide analogs of SLIGRL in which an amino acid has been substituted with a non-natural amino acid. A large variety of different non-natural amino acids has been substituted in these examples. Moreover, these peptide analogs exemplify a substitution at every position of SLIGRL, except for the final leucine. However, the activity shown by peptide numbers 1 and 2 in which the final leucine has been deleted clearly indicate that the final leucine is not necessary for activity. Accordingly, Claim 1 is proper according to the requirements of 35 U.S.C. § 112, first paragraph.

The Examiner rejected Claim 23 under 35 U.S.C. § 112, first paragraph, for enablement and written description for the limitation “a peptide derivative thereof having similar biological activity to SLIGRL.” Claim 23 has been cancelled without prejudice.

The Examiner rejected Claim 2 under 35 U.S.C. § 112, first paragraph, for reasons of record. The Examiner suggested submitting an article demonstrating the use of A549 cells as an accepted model for airway inflammation. At the interview, Examiner agreed to review Claim 2 along with the references submitted with the Response dated October 1, 2004. The Declaration submitted October 1, 2004 outlined the experiments in which preferred compounds were tested in human cells. In paragraph 19 of the Declaration, the assay utilizes A549 cells, which were initiated from a human alveolar cell carcinoma. The references submitted with the Declaration show the A549 cells to be human cell line. Accordingly, Claim 2 directed to a method for use in humans is enabled.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

#### CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

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The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

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